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<b>IN THE UNITED STATES PATENT AND TRADEMARK OFFICE</b>	Application No.	09/986,381
	Filing Date	November 8, 2001
	First Named Inventor	Steven S. Sommer, et al.
	Group Art Unit	1637
	Examiner Name	Shar S. Hashemi
	Attorney Docket No.	1954-360
Title of the Invention: <i>Measurement of Mutation Load Using the p53 Gene in Human Cells From Paraffin Embedded Tissues</i>		

INFORMATION DISCLOSURE STATEMENT

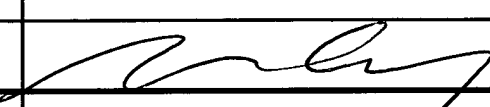
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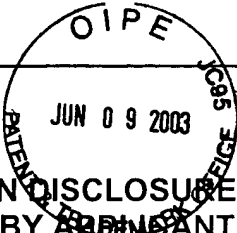
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Dear Sir:

Under the provisions of 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants submit herewith copies of publications that the Office may wish to consider in examination of the subject application. The publications are listed on the attached form PTO/SB/08.

Pursuant to the provisions of 37 C.F.R. § 1.17, enclosed is a check for \$180.00. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 02-2135. An additional copy of this document is enclosed.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
(PTO/SB/08)**

Complete if Known

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Examiner Name	Shar S. Hashemi

Sheet	1	of	3	Attorney Docket Number	1954-360
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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	A	2002/0098166	A1	HAVEMANN et al.	07-25-2002
	B	6,071,726	A	DIAMANDIS et al.	06-06-2000
	C	6,342,217	B1	LINK, JR. et al.	01-29-2002

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee of Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
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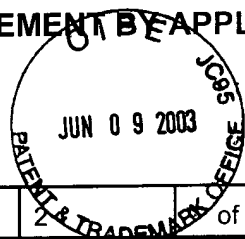
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<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code.

<sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached. AB indicates that only an English language abstract is attached.

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**



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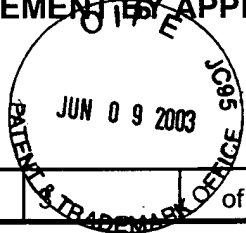
Attorney Docket Number 1954-360

## **OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	D	JANE COLE, et al., "International Commission for Protection Against Environmental Mutagens and Carcinogens"; Mutation Research, 304 (1994) pp33-105, 1994.
	E	ALAN S. JONASON, et al., "Frequent clones of p53-mutated keratinocytes in normal human skin"; Proc. Natl. Acad. Sci. USA, Vol. 93, pp14025-14029, November 1996.
	F	S. PERWEZ HUSSAIN, et al., "Increased p53 mutation load in nontumorous human liver of Wilson disease and hemochromatosis: Oxyradical overload diseases"; PNAS, pp12770-12775, Vol. 97, No. 23, November 7, 2000.
	G	S. PERWEZ HUSSAIN, et al., "Mutability of p53 Hotspot Codons to Benzo(a)pyrene Diol Epoxide (BPDE) and the Frequency of p53 Mutations in Nontumorous Human Lung"; Cancer Research 61, pp6350-6355, September 1, 2001.
	H	FERNANDO AGUILAR, et al., "Aflatoxin B <sub>1</sub> induces the transversion of G→T in codon 249 of the p53 tumor suppressor gene in human hepatocytes"; Proc. Natl. Acad. Sci. USA, Vol. 90, pp.8586-8590, September 1993.
	I	LOREL M. COLGIN, et al., "The unexpected landscape of in vivo somatic mutation in a human epithelial cell lineage"; PNAS, February 5, 2002, Vol. 99, No. 3, pp14437-14442.
	J	LESLIE RECIO, et al., "DNA sequence analysis of in vivo hprt mutation in human T lymphocytes"; Mutagenesis, Vol. 5, No. 5, pp505-510, 1990.
	K	NEAL OF CARIELLO, et al., "Analysis of Mutations Occurring at the Human hprt Locus" J. Mol. Biol. (1993) 231, pp41-57.
	L	VERNON E. WALKER, et al., "Frequency and Spectrum of Ethylnitrosourea-induced Mutation at the hprt and lacI Loci in Splenic Lymphocytes of Exposed lacI Transgenic Mice"; CANCER RESEARCH 56, pp4654-4661, October 15, 1996.
	M	THOMAS R. SKOPEK, et al., "Relative Sensitivity of the Endogenous hprt Gene and lacI Transgene in ENU-Treated Big Blue™ B6C3F1 Mice"; Environmental and Molecular Mutagenesis 26:9-15 (1995).
	N	THOMAS R. SKOPEK, et al., "Mutagenic Response of the Endogenous hprt Gene and lacI Transgene in Benzo[a]pyrene-Treated Big Blue™ B6C3F1 Mice"; Environmental and Molecular Mutagenesis 28:376-384 (1996).
Examiner Signature		Date Considered

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	O	OLGA O. MOTORNA, et al., "Analysis of lacI mutations in Big Blue® transgenic mice subjected to parasite-induced inflammation"; Mutation Research, 484 (2001), pp69-76.
	P	SUSAN E. ANDREW, et al., "A novel lacI transgenic mutation-detection system and its application to establish baseline mutation frequencies in the scid mouse"; Mutation Research, 357 (1996), pp57-66.
	Q	TETSUYA ONO, et al., "Age-associated increase of spontaneous mutant frequency and molecular nature of mutation in newborn and old lacZ-transgenic mouse"; Mutation Research, 447 (2000), pp165-177.
	R	GREGORY R. STUART, et al., "Mutation Frequency and Specificity With Age in Liver, Bladder and Brain of lacI Transgenic Mice"; Genetics Society of America, 154:pp1291-1300, (March 2000).
	S	P.D. LEWIS, et al., "Spontaneous mutation spectra in supF: comparative analysis of mammalian cell line base substitution spectra"; Mutagenesis, Vol. 16, No. 6, pp503-515, 2001.
	T	TAKEHIKO NOHMI, et al., "Recent advances in the protocols of transgenic mouse mutation assays"; Mutation Research, 455 (2000), pp191-215.
	U	JOHN A. HEDDLE, et al., "In Vivo Transgenic Mutation Assays"; Environmental and Molecular Mutagenesis, 35:253-259 (2000).
	V	SUSAN E ANDREW, et al., "Base transitions dominate the mutational spectrum of a transgenic reporter gene in MSH2 deficient mice"; Oncogene (1997) 15, pp123-129.
	W	SUSAN E. ANDREW, et al., "Mutagenesis in PMS2- and MSH2-deficient mice indicates differential protection from transversions and frame shifts"; Carcinogenesis, Vol. 21, No. 7, pp1291-1295, 2000.
	X	KENTARO HORIKAWA, et al., "Frequent detection of T cells with mutations of the hypoxanthine-guanine phosphoribosyl transferase gene in patients with paroxysmal nocturnal hemoglobinuria"; Blood 1 January 2002, Vol. 99, No. 1, pp24-29.
	Y	CLIVE R. TAYLOR, M.D., Ph.D., et al., "Antigen Retrieval for Immunohistochemistry Status and Need for Greater Standardization"; Applied Immunohistochemistry, 4(3):144-166, 1996.

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